

10/630,879

Attorney Docket No. 14498

SPECIFICATION AMENDMENTS

Please delete the paragraph beginning on page 13, line 19 and ending on page 14, line 16 and insert the following paragraph as follows:

In another embodiment, the present invention is a method of making a pharmaceutical composition in the form of a perforated layered tablet. In one embodiment, the method comprises making pharmaceutical composition in the form of a perforated layered tablet, such as the perforated layered tablet ~~20~~ 16 shown in Figure 2. The method comprises providing a pharmaceutical composition comprising one or more than one first outer layer ~~22~~ 20, where the outer layer comprises one or more than one substantially water-insoluble polymer, or the outer layer comprises one or more than one substantially water-soluble polymer; and an inner polymer layer 22 comprising one or more than one enteric polymer and a drug, where the enteric polymer is substantially hydrophobic and substantially soluble in a substantially aqueous environment above a pH of about 5. Then, the first outer polymer layer ~~22~~ 20 is compressed into a die. Next, the enteric polymer and a drug are combined to form a mixture. Next, the mixture is compressed into the first outer polymer layer ~~22~~ 20 to form an inner polymer layer ~~26~~ 22. Next, a second outer polymer layer ~~24~~ 18 is compressed into the inner polymer layer ~~26~~ 22 to form a tablet ~~28~~ 16. Next, a perforation ~~30~~ 26 is formed in the tablet ~~28~~ 16. In a preferred embodiment, the tablet is a cylindrically shaped tablet and the perforation extends completely through the center of the cylindrically shaped tablet. In another embodiment, the method additionally comprises mixing one or more than one binder into the enteric polymer and the drug to form the mixture and compressing the mixture into the first outer polymer layer ~~22~~ 20. In a more preferred embodiment, the method comprises compressing the first outer polymer layer ~~22~~ 20 into a die with a press. Then, the inner polymer layer ~~26~~ 22 is compressed into the first outer polymer layer ~~22~~ 20 in the die. Next, the second outer polymer layer ~~24~~ 18 is compressed into the inner polymer layer ~~26~~ 22 in the die to form the layered tablet ~~28~~ 16. Next, the perforation ~~30~~ 26 is formed in the layered tablet ~~28~~ 16 with a drill. In one embodiment, the press is Carver press and the layered tablet is compressed under about a 6,000 psi compression force. Other methods for fabricating perforated layered tablets of the present invention can be used, such as modifying punches of a rotary multilayer tablet press, as used, for example in a commercial process, as will

10/630,879

Attorney Docket No. 14498

be understood by those of skill in the art with reference to this disclosure.